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K060031 page 1/2

510(k) SUMMARY

NAME OF FIRM: DePuy Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581

510(k) CONTACT: Keli Hankee
Clinical Research Associate

TRADE NAME: DePuy Modular M Heads

COMMON NAME: Femoral Heads

CLASSIFICATIONS:

888.3350: Hip joint metal/polymer semi-constrained cemented prosthesis
888.3358: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis

DEVICE PRODUCT CODES:

87 JDI and 87 LPH

SUBSTANTIALLY EQUIVALENT DEVICES:

- DePuy ULTIMA Unipolar Femoral Heads: K033273 (submitted as Pinnacle™ Acetabular System)
- DePuy Articul/eze Femoral Heads: K980513
- DePuy 36 mm Femoral Heads: K980513, K851422 (cleared through internal documentation.)

DEVICE DESCRIPTION AND INTENDED USE:

The subject DePuy Modular M Heads are manufactured from wrought Co-Cr-Mo alloy and are available in:

- 40, 44, and 48 mm diameters with a 12/14 Articul/eze taper and –2, +1.5, +5, +8.5, +12 and +15.5 mm neck lengths. All of the Articul/eze taper femoral heads have an internal taper that mate with a corresponding external taper on compatible cemented or cementless femoral stems (Exhibit III).
- 40 and 44 mm diameters with an 11/13 S-ROM taper and -3, +0, +3, +6, +9 and +12 mm neck lengths. The 48 mm heads with the 11/13 S-ROM taper are available in +0, +3, +6, +9 and +12 mm neck lengths. All of the S-ROM taper

femoral heads have an internal taper that mate with a corresponding external taper on compatible cemented or cementless femoral stems (Exhibit III).

The subject device is designed to articulate with the Pinnacle™ Marathon® ES3 Liners (K033273) inside a Pinnacle™ Acetabular System shell (K033338) in cementless applications.

DePuy Modular M Heads are indicated for use in total hip replacement procedures. Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total hip replacement is indicated in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

The DePuy Modular M Heads are indicated for use with the Pinnacle® Acetabular Cup in cementless application.

BASIS OF SUBSTANTIAL EQUIVALENCE:

Based on design, method of manufacture, intended use, available diameter and indication, the subject device is found to be substantially equivalent to the comparison device, K033273.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 1 2006

Ms. Keli K. Hankee
Clinical Research Associate
DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K060031
Trade/Device Name: DePuy Modular M Heads
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis.
Regulatory Class: Class II
Product Code: LPH, JDI
Dated: January 4, 2006
Received: January 5, 2006

Dear Ms. Hankee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

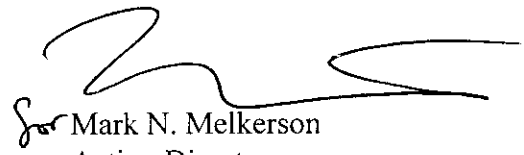
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Mark N. Melkerson
Acting Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K060031

Device Name: DePuy Modular M Head

Indications for Use:

DePuy Modular M Heads are indicated for use in total hip replacement procedures. Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total hip replacement is indicated in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
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4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

The DePuy Modular M Heads are indicated for use with the Pinnacle® Acetabular Cup in cementless application.

Prescription Use X AND/OR Over-The-Counter Use No

(Title 21 CFR Part 801 Subpart D) (Title 21 CFR Part 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060031